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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,368	09/20/2004	Sven Morein	026220-00054	4091

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ARENT FOX LLP
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WASHINGTON, DC 20036

EXAMINER

AHMED, HASAN SYED

ART UNIT	PAPER NUMBER
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1615

NOTIFICATION DATE	DELIVERY MODE
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12/03/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com
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Office Action Summary	Application No. 10/507,368	Applicant(s) MOREIN ET AL.	
	Examiner HASAN S. AHMED	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-42 is/are pending in the application.
- 4a) Of the above claim(s) 3, 10-18 and 21-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-9, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/20/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicants' amendment and response, filed on 15 August 2008.

* * * * *

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 20 September 2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, all references have been considered. An initialed copy of the IDS is enclosed.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5-9, 19, and 20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 376 331 ("Tsuru") in view of WO 01/66088 ("Holmberg").

Tsuru teaches slow release drug delivery granules (see page 2, line 42) comprising:

- the drug absorbed into porous particles of instant claims 1 and 2 (see page 2, lines 48 and 51);
- the calcium phosphate of instant claim 1 (see page 3, line 14); and
- the particle size of instant claims 5 and 6 (see page 3, line 46).

Tsuru explains that the disclosed particles are beneficial because they result in, "...controllable and good prolonged effect of the drug release..." See page 2, line 9.

While Tsuru does not explicitly teach the pore sizes of instant claims 7-9, it is the position of the Examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable pore size through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in pore size will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

The prior art teaches a pore size of 1nm to 10um (see page 3, line 42).

Tsuru differs from the instant application in that it does not disclose NO-donating NSAIDs.

Holmberg teaches a drug delivery system comprising:

- the NO-donating NSAID of instant claim 1, said NSAID adsorbed into particles (see page 21, lines 29-30);
- the oily form of instant claim 2 (see page 11, lines 1-2);

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- and the naproxen of instant claims 19 and 20 (see page 5, line 18) (the empirical formula of instant claim 20 is deemed to be an inherent description of naproxen).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a solid drug delivery composition comprising a NO-donating NSAID absorbed onto a porous particle, as taught by Tsuru in view of Holmberg. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it results in controllable and good prolonged effect of the drug release, as explained by Tsuru.

* * * * *

Response to Arguments

Applicants' arguments filed on 15 August 2008 have been fully considered but they are not persuasive.

1. Applicants argue that, "...dibasic calcium phosphate and dibasic calcium phosphate anhydrous (Ca to P atomic ratio of 1 using FUJICALCIN) are different than the porous granules of Tsuru et al., which have an atomic ratio of Ca to P...of 1.3 to 1.8." See remarks, page 10.

Examiner respectfully submits that the prior art reads on the instant application as claimed. Instant claim 1, as currently constructed, recites "dibasic calcium phosphate, anhydrous," which is a genus that includes FUJICALCIN, but also includes species of dibasic calcium phosphate and dibasic calcium phosphate anhydrous which have an "m" value greater than 0 (as "m" is defined in the remarks on page 10). As

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such, the calcium phosphate of Tsuru reads on the broader claim language of instant claim 1.

2. Applicants argue that Tsuru, "...also fails to teach or suggest the other porous particles of claim 1..." See remarks, page 10.

Examiner respectfully submits that calcium phosphate alone meets the porous particles limitation of claim 1 since the list of porous particles are recited as a Markush group.

3. Applicants argue that, "...Tsuru et al. discloses "slow release drug delivery granules," whereas some embodiments of the present invention provide a large percentage of drug released..." See remarks, page 11.

Examiner respectfully submits that such a comparison is not relevant to a showing of distinction between the prior art and the instant application since one variable relates to release rates while the other relates to volume released.

4. Applicants argue that Holmberg, "...discloses a pharmaceutical composition in the form of an emulsion pre-concentrate, comprising one or more of NO-releasing NSAIDs, one or more surfactants, and optionally an oil or semi-solid fat..." See remarks, page 11.

The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising,' the terms containing' and mixture' are open-ended."). See MPEP 2111.03.

Thus, examiner respectfully submits that the instant claims are open to additional ingredients such as surfactants, oil, or fat.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 3, 10-18, and 21-42 drawn to an invention nonelected with traverse in the reply filed on 22 January 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

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